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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Qing Yang

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JORDAN AND HAMBURG LLP  
122 EAST 42ND STREET  
SUITE 4000  
NEW YORK, NY 10168

EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,353	<b>Applicant(s)</b> YANG, QING	
	<b>Examiner</b> RUSSELL S. NEGIN	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 53-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Comments***

Applicants' amendments and request for reconsideration in the communication filed on 9 January 2009 are acknowledged and the amendments are entered.

Claims 53-70 are pending and examined in the instant Office action.

### ***Information Disclosure Statement***

The information disclosure statement of 9 January 2009 is considered.

### ***Withdrawn Objections/Rejections***

ALL of the rejections from the previous Office action are WITHDRAWN in view of cancellation the previous set of claims. ALL of the rejections in the instant Office action are NEWLY applied and necessitated by applicant's amendments.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following rejection is necessitated by applicant's amendments:

Claims 53-70 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 53-70 are drawn to a method of estimating arterial delay and arterial dispersion.

As stated in MPEP 2106, section IV, if the claims are found to cover a judicial exception then the claims will be evaluated for providing a practical application of the judicial exception (*i.e.*, Law of Nature, Natural Phenomenon, or an Abstract Idea). This is in line with the recent decision in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In the instant case, the claims are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. In order for a claim to provide a practical application, the claim **must meet** the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008)). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept **may have a practical application**, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (*i.e.* a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus or (2) transforms a particular article to a different state or thing.

In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps of *in silico* information manipulation. Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

Further, the method claims (claims 53-70) are not so tied to another statutory class of invention because the **method** steps that are critical to the invention are "not tied to any **particular apparatus** or **machine**" and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

It is noted that while instant claim 54 recites storage to a computer, this computer does not constitute a significant tie to a particular apparatus, but rather, the step of recording is insignificant post-solution activity.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

#### **INDEFINITENESS**

Claims 53-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 is indefinite because while it recites in step a “an estimated  $t_1$  is the transit time of a contrast agent ...” it is unclear as to what the metes and bounds of such an estimation on the transit time comprises. (i.e. what particular form of estimation is used).

Claim 53 is additionally indefinite because while the function in step a recites use of the variable  $\sigma_1$ , (step b) the variable  $\sigma_1$  is not initialized until a later step (step c) of the instant claim.

Claim 53 is additionally indefinite because while the function  $h_a(t)$  in step a of the method comprises a single variable, the function  $h_a(t, \alpha_1=0)$  comprises more than one variable. It is unclear whether these are the same function, or different. If the same, then it is not understood as to the metes and bounds of the function  $h_a(t)$  with a single variable in the form of a function with two variables  $h_a(t, \alpha_1=0)$ .

Claim 53 is further indefinite because it is not known as to what the function  $R_e(t)$  comprises. (It is recited in step d of instant claim 53). Specifically, it is not until claim 63 that an example of a definition of the function is introduced into the set of claims.

Claim 53 is further indefinite because it is not known what the “**hermocrit**” correction constant comprises.

Claim 53 is further indefinite because it is not known as to the relation of step e of the instant claim and the remaining steps of the method. Specifically, step e of the claim does not specify the optimization algorithm for the instant claim and does not specify the definitions of the  $t_2$ ,  $\alpha_2$ , and  $\sigma_2$ , and how each variable relates to  $t_1$ ,  $\alpha_1$ , and

$\sigma_1$ . Additionally, it is not recited as to the roles of these parameters in the derivation of the simulated concentration curve  $C_s(t)$ .

The term "late arrival contrast agent peak" in claim 57 is a relative term which renders the claim indefinite. The term "late arrival" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not known as to relative to what quantity a late arrival qualifies as being late.

Claim 61 recites the limitation "said second gamma-variate function" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim. A second gamma variate function is not recited earlier in the instant claim.

The term "small lumen" in claim 66 is a relative term which renders the claim indefinite. The term "small lumen" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not known as to relative to what quantity a small lumen becomes small.

The term "more robust fitting process" in claim 66 is a relative term which renders the claim indefinite. The term "more robust" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not known as to relative to what level of robustness a "robust" fitting process becomes *more* robust.

## ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. From the instant claimed limitations, it is not known how to execute certain mathematical limitations of the instant claims that comprise formulae and optimization.

1. Instant claims 53-70 recite the function  $h_a(t)$  with a single variable and later recites the same function with multiple variables as  $h_a(t, \alpha_1=0)$ . Instant claim 53 later recites (in step e) outputting estimated and optimized tissue mean transit time and dispersion using a mutually exclusive set of variables that do not overlap the initial set. Specifically, claim 53 (and claims 54-70) do not give further understanding as to the relation between these first ( $t_1$ ,  $\alpha_1$ , and  $\sigma_1$ ), and second ( $t_2$ ,  $\alpha_2$ , and  $\sigma_2$ ) sets of variables.

2. The instant specification is silent on the use of multiple variables for the function  $h_a(t)$ . Additionally, while the specification teaches that  $t_1$ ,  $\alpha_1$ ,  $\sigma_1$ ,  $t_2$ ,  $\alpha_2$ , and  $\sigma_2$  are amongst the seven parameters (see top of page 18 of the specification), and

equation 13 on page 18 indicates how these parameters calculate physiological parameters of interest, there is no equation or comparison between the first ( $t_1$ ,  $\alpha_1$ , and  $\sigma_1$ ), and second ( $t_2$ ,  $\alpha_2$ , and  $\sigma_2$ ) sets of variables taught in the instant specification. Although the specification does teach methods for optimization (i.e. least squares and singular value decomposition), since one of skill in the art is forced to guess at such a relation between the two sets of variables, the process of optimizing the mean transit time and arterial dispersion requires undue experimentation.

3. The closest prior art of the patent of Ostergaard [US Patent 7,069,068; issued 27 June 2006; filed 23 March 2000] teaches similar convolutions, optimization algorithms, and haemodynamic indices as those recited in the instant claims. However, the relations between the variables of interest are clearly stated throughout the disclosure of Ostergaard such that one of skill in the art would not have to guess at determining the relevant indices.

4. The claims make use of the vascular transport function  $h_a$  from which the user must guess as to whether there is one ( $t$ ) or two ( $t$ ,  $\alpha_1$ ) dependent variables. Similarly there is a lack of clear relation between the first ( $t_1$ ,  $\alpha_1$ , and  $\sigma_1$ ), and second ( $t_2$ ,  $\alpha_2$ , and  $\sigma_2$ ) sets of dispersion times and constants. In the absence of a clear relation between the variables and parameters utilized in the instant set of claims (as opposed to the prior art of Ostergaard which shows a working relationship between parameters and

variables), one of skill in the art must guess at how to conduct the optimization of the instant set of claims. Such guessing amounts to UNDUE EXPERIMENTATION.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

#### WRITTEN DESCRIPTION

Claims 53-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims 53-70 recite the function  $h_a(t)$  with a single variable and later recites the same function with multiple variables as  $h_a(t, \alpha_1=0)$ . The specification only discloses the function  $h_a(t)$  with a single variable and not multiple variables (see for example, page 3 of the specification). Consequently, this function,  $h_a(t, \alpha_1=0)$ , constitutes NEW MATTER.

#### ***Response to Arguments***

Applicant's arguments with respect to the instant claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/  
Russell S. Negin  
3 June 2009

/Marjorie Moran/  
Supervisory Patent Examiner, Art Unit 1631